



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3315-FN]

Medicare and Medicaid Programs; Continued Approval of the American Association of Diabetes Educators as an Accrediting Organization for Diabetes Self-Management Training Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Association of Diabetes Educators (AADE) for continued recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training (DSMT) to Medicare beneficiaries.

DATES: This final notice is effective [OFR insert date of publication in the **Federal Register**] through [OFR insert date 6 years after the date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT:

Kristin Shifflett, (410) 786-4133.

Jacqueline Leach, (410) 786-4282.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive outpatient diabetes self-management training (DSMT) when ordered by the physician (or qualified non-physician

practitioner) treating the beneficiary's diabetes, provided certain requirements are met by the provider. Pursuant to our regulations at 42 CFR 410.141 (e)(3), we use national accrediting organizations (NAOs) to assess whether provider entities meet Medicare requirements when providing DSMT services for which Medicare payment is made. If a provider entity is accredited by an approved accrediting organization, it is "deemed" to meet applicable Medicare requirements.

A NAO must meet the standards and requirements specified by the Secretary of the Department of Health and Human Services in our regulations under part 410, subpart H, to qualify for deeming authority. The regulations pertaining to application procedures for NAOs for DSMT are specified at §410.142 (CMS process for approving national accreditation organizations).

A NAO applying for deeming authority must provide us with reasonable assurance that the accrediting organization requires accredited entities to meet requirements that are at least as stringent as our requirements.

We may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish DSMT. The accreditation organization, after being approved and recognized by CMS, may accredit an entity to meet one of the sets of quality standards in §410.144 (Quality standards for deemed entities).

Section 1865(a)(2) of the Social Security Act (the Act) requires that we review the applying accreditation organization's requirements for accreditation, as follows:

- Survey procedures.
- Ability to provide adequate resources for conducting required surveys.
- Ability to supply information for use in enforcement activities.

- Monitoring procedures for providers found out of compliance with the conditions or requirements.
- Ability to provide CMS with necessary data for validation.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On April 24, 2015, we published a proposed notice in the **Federal Register** (80 FR 23009) entitled “Application by the American Association of Diabetes Educators for Continued Deeming Authority for Diabetes Self-Management Training,” announcing the receipt of an application from AADE for continued recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries.

In that notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and our regulations at §410.142 and §410.143, we conducted a review of AADE’s national accreditation organization based on the criteria set forth in §410.142(b), which include, but are

not limited to the following: (1) a review of the national accreditation organization's operations and office to verify information in the organization's application and assess the organization's compliance with its own policies and procedures; (2) evaluating accreditation results or the accreditation status decision making process; and (3) interviewing the organization's staff.

The April 24, 2015 proposed notice also solicited public comments on the ability of AADE to continue to develop standards that meet or exceed the Medicare conditions for coverage and apply them to entities furnishing outpatient services. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

AADE's application to continue as an accredited NAO to deem entities for the purposes of DSMT is approved for a period of 6 years. The accreditation is effective on **[OFR insert date of publication in the Federal Register]**. This approval is subject to renewal subsequent to the receipt of an application from the AADE and subject to review, evaluation, and approval of its program.

Based on our review and observations described in section II of this final notice, we approve AADE as a national accreditation organization for entities furnishing DSMT that request participation in the Medicare program, effective **[OFR insert date of Publication date in the Federal Register)** through **[OFR insert date 6 years after date of publication date in the Federal Register]**.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review

by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

CMS-3315-PN

Dated: September 16, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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